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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,201	09/26/2001	John H. Kenten	IGN-2005	2119

7590

12/30/2002

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 12/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/964,201

Applicant
Kenten et al

Examiner
Fozia Hamud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-79, 84, 85, and 87-93 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 76 and 84 is/are allowed.
- 6) ☒ Claim(s) 77-79, 85, and 87-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

1. Receipt of Applicant's preliminary amendment filed in Paper No.10 filed on 26 September 2001 is acknowledged. Claims 1-75, 80-83 86 and 94-100 are canceled.

Thus claims 76-79, 84-85, 87-93 are pending and under consideration by the Examiner.

Claim objections

2. Claims 87-93 are objected to because of the following informalities:

Claim 87 is objected to because it is dependent on canceled claims 1, 20, 41 and 58.

Claims 88-93 are objected to, insofar as they depend on claim 87. Appropriate correction is required.

Specification:

3a. It is noted that this application a divisional of Application 09/026,276,"now Patent No. 6,319,503". If applicant desires priority under 35 U.S.C. 120 based upon this Application 09/026,276, specific reference to the this application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the

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prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

3b. The amendment to the specification filed on 04 January 2002, in Paper NO:4, has not been entered, because it is improper. The desired changes must be shown by brackets (for deleted matter) or underlying (for added matter).

Claim rejections-35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4a. Claims 77-79, 85, 87-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4b. Claim 77, recites “ubiquitin fused to two or more non-contiguous epitope-containing segments, each epitope-containing segment, comprising one or more identical or non-identical epitopes.... ”, and claims 78-79, recite “ubiquitin fused to a single epitope containing segment, comprising one, two or more identical or non-identical epitopes.... ”, which render the claims vague and indefinite. Instant specification refers “epitopes” as recombinant immunologically active heterologous antigens, (see page 6, lines 17-19). Instant invention takes advantage of the fact that ubiquitin is immunologically silent, and that administration of a ubiquitin fusion protein into an animal elicits an immune response directed toward the heterologous protein attached to ubiquitin and not toward ubiquitin. Therefore, it is unclear, as to how many immunologically active heterologous antigens are attached to ubiquitin and which one is the immune response directed to. It is also unclear, if there are two or more non identical epitopes, should each epitope elicit its own immune response?. Appropriate correction is required.

4c. claim 85, recites “..... substantially similar.....”, which renders the claim indefinite, because it is unclear how similar, does this mean total castration or less than total castration? Appropriate correction is required.

4d. Claim 87, depends from canceled claims 1, 20, 41 and 58. Claims 20 and 58 also recite “..one, tow or more identical or non identical epitopes”. Therefore, it is unclear, the level of which epitope should be reduced, after the administration of ubiquitin fusion proteins comprising more than one epitope into an animal. Appropriate correction is required.

Claims 88-93 are rejected as being vague and indefinite insofar as they depend on claim 87 for the limitations set forth directly above.

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Conclusion

5. Claims 76 and 84 are allowable.

Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays and Thursdays and every other Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
26 December 2002


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